

### **Remarks**

Claims 1-3, 5-22, and 24-31 are pending in the application. By this Reply, claims 1, 28, and 30 are amended. No new matter has been added. Applicants respectfully reconsideration of the pending claims in view of the foregoing amendments and following remarks.

In the Office Action, Claim 24 was rejected under 35 U.S.C. § 102(b) over U.S. Patent No 6,290,728 to Phelps et al. (hereinafter “Phelps”). Applicants respectfully traverse this rejection.

Regarding independent claim 24, Phelps does not disclose or suggest a stent comprising, *inter alia*, a plurality of “end struts being radially thinned along their lengths relative to the main body.” Instead, Phelps discloses various bypass stents, including at least one stent (FIG. 11) that appears to have legs 30 expanding outwardly from the main body of the stent 34. While the legs appear to taper along their lengths (i.e., circumferentially thinned), they do not appear to be radially thinned along their lengths, nor does Phelps disclose any such radial thinning. Indeed, the examiner’s rejection does not address this feature of claim 24. Rather, the examiner merely alleges that Phelps discloses “end struts being thinned along their lengths,” without addressing the feature of radially thinned end struts, as recited in claim 24.

In addition, claims 1-3, 5-17, 25, 26, and 28-31 were rejected under 35 U.S.C. § 103(a) over Phelps in view of U.S. Patent No. 6,241,762 to Shanley. Applicants respectfully traverse this rejection.

Regarding independent claim 1, Phelps does not disclose or suggest a stent comprising, *inter alia*, an “end structure including predefined bend locations comprising areas of reduced radial wall thickness as compared to areas of adjacent locations for facilitating flaring of the end structure relative to the main body.” Indeed, the examiner acknowledged that “Phelps does not disclose the use of notches to facilitate bending.” See Office Action dated October 17, 2007, page 3, paragraph 3. Furthermore, as

discussed above in connection with claim 24, Phelps does not disclose or suggest a stent having an end structure with a reduced radial wall thickness.

Shanley does not overcome the above-noted deficiencies of Phelps. The examiner relies on Shanley for the alleged teaching of “the use of notches for the purpose of bending sections of a stent.” Applicants disagree with the examiner’s interpretation of Shanley and submit that any alleged teaching of Shanley is not properly applied to the present claims.

First, applicants submit that Shanley only teaches the use of ductile hinges 32 to accommodate mechanical strain during radial expansion and compression of the tissue supporting device 20. Nowhere does Shanley disclose or suggest that the hinges 32 facilitate flaring of any structure of the tissue supporting device 20. That is, the ductile hinges 32 of Shanley may facilitate a circumferential bending that accommodates expansion or enhanced crimping of the device 20, but they do not in any way facilitate flaring (i.e., a radially-outward deflection) of an end structure, as recited in claim 1.

Second, Shanley, like Phelps, does not disclose or suggest a stent having an end structure with a reduced radial wall thickness. Indeed, the examiner does not rely on Shanley for such a teaching.

Third, persons skilled in the art would recognize the importance of optimizing the surface area of a stent that contacts, or covers, the tissue of a vessel wall where the stent is being implanted. Such an optimal degree of stent-to-vessel wall coverage is needed to prevent prolapsed after stent implantation, which could subsequently lead to restenosis. An optimal amount of coverage may be achieved by the present disclosure because the end structure is thinned to facilitate flaring. To the contrary, Phelps teaches circumferentially-tapered flanges 30 and Shanley teaches circumferentially-extending hinges 32, both of which reduce the amount of stent surface area in contact with the vessel wall. Applicant submits that the narrowing flanges 30 and hinges 32 of Phelps and Shanley, respectively, can cause prolapse and restenosis of the vessel wall, unlike the present disclosure, which maintains an optimal planar surface area in contact

with the vessel wall while reducing the radial thickness of the end structure to facilitate flaring.

Therefore, applicants submit that Phelps and Shanley, both independently and in combination, fail to disclose or suggest the features of independent claim 1. Further, claims 2, 3, 5-13, and 25, which depend from claim 1, are allowable for at least the same reasons that claim 1 is allowable as well as for their own unique features. Accordingly, applicants request that the § 103 rejection of claims 1-3, 5-13, and 25 be withdrawn.

Regarding independent claims 14 and 28, Phelps and Shanley, alone and in combination, fail to disclose or suggest the features of these claims for reasons similar to those discussed above in connection with independent claim 1. Additionally, claims 15-22 and 26, which depend from claim 14, are allowable for at least the same reasons that claim 14 is allowable as well as for their own unique features, and claim 29, which depends from claim 28, is allowable for at least the same reasons that claim 28 is allowable as well as for its own unique features. Accordingly, applicants request that the § 103 rejection of claims 14-22, 26, 28 and 29 be withdrawn.

Regarding independent claim 30, Phelps does not disclose or suggest a method for implanting a stent including, *inter alia*, positioning the stent such that the main body of the stent is located within a first vessel and the end structure extends into a second vessel. To the contrary, Phelps discloses methods for implanting a stent into a myocardial wall (MYO) to open a conduit from the left ventricle LV to the coronary artery CA. See, e.g., col. 6, line 5, et seq.

In the Office Action, the examiner alleges:

Phelps further discloses a stent implanted at the junction between two vessels, with the main body located in the first vessel and the end structure conformed to an interior surface of the second vessel (fig. 8). The stent of Phelps ... is implanted at the junction of two blood vessels (fig. 8).

Applicants disagree and submit that the examiner's statement is simply not accurate. As previously stated, Phelps discloses implanting a stent into a myocardial wall (MYO)

to create a passageway from the left ventricle LV to the coronary artery CA. Simply stated, the passageway through the myocardial wall, created by implantation of the stent in the myocardial wall, is not a blood vessel. Persons having ordinary skill in the art pertaining to cardiovascular physiology would appreciate and understand that a blood vessel has a vessel wall, and particular functional and biochemical characteristics are associated with a vessel wall. The skilled artisan would also appreciate and understand that the passageway through the myocardial wall created by the stent does not have a vessel wall and the myocardial wall does not have the functional and biochemical characteristics associated with a vessel wall.

Applicants therefore submit that Phelps does not disclose or suggest positioning the stent such that the main body of the stent is located within a first vessel and the end structure extends into a second vessel, as recited in independent claim 30. Shanley does not overcome the above-noted deficiency of Phelps, nor is it relied upon for such teaching. Instead, Shanley is merely relied upon for its alleged teaching of the use of notches for bending sections of a stent.

Therefore, applicants submit that Phelps and Shanley, both independently and in combination, fail to disclose or suggest the features of independent claim 30. Further, claim 31, which depends from claim 30, is allowable for at least the same reasons that claim 30 is allowable as well as for its own unique features. Accordingly, applicants request that the § 103 rejection of claims 30 and 31 be withdrawn.

Additionally, claims 18-22 and 27 were rejected under 35 U.S.C. § 103(a) over U.S. Publication Number 2004/0186555 by Bonsignore et al. (hereinafter “Bonsignore”) in view of Shanley. Applicants respectfully traverse this rejection.

Regarding independent claim 18, Bonsignore does not disclose or suggest a stent comprising, inter alia, “end struts defining notches for facilitating flaring of the end struts relative to the main body.” Indeed, the examiner acknowledged that “Bonsignore does not disclose the use of notches to facilitate bending.” See Office Action dated October 17, 2007, page 4, paragraph 5.

Shanley does not overcome the above-noted deficiency of Bonsignore. Nonetheless, the examiner relies on Shanley for the alleged teaching of “the use of notches for the purpose of bending sections of a stent [sic].” The examiner’s reliance is improper, erroneous, and does not obviate claim 18 for at least the following reasons.

First, as discussed above, Shanley only teaches the use of ductile hinges 32 to accommodate mechanical strain during radial expansion and compression of the tissue supporting device 20. Nowhere does Shanley disclose or suggest that the hinges 32 facilitate flaring of any structure of the tissue supporting device 20. That is, the ductile hinges 32 of Shanley may facilitate a circumferential bending that accommodates expansion or enhanced crimping of the device 20, but they do not in any way facilitate flaring (i.e., a radially-outward deflection) of an end strut. Therefore, Shanley does not disclose or suggest notches for facilitating flaring, as recited in claim 18.

Second, assuming *arguendo* that Shanley’s teachings can be translated to notches that facilitate flaring (which applicants adamantly reject), such notches would be cut into the wall of the stent and reduce the thickness of the stent wall at the notched region. However, Bonsignore teaches away from such a reduction in the thickness of the stent wall. Specifically, Bonsignore addresses the problem of twisting struts by assuring that “the widths of the struts, hoops and bridges are equal or less than the wall thickness of the tube” so as to preserve certain preferred stress distributions within the stent. See Bonsignore, paras. [0051]-[0052]. By notching the bending sections of the stent, as alleged by the examiner, the wall thickness of the tube would be decreased at the notched regions, and the widths of the struts, hoops and bridges would then be greater than the wall thickness of the tube, which is contrary to the explicit teachings of Bonsignore designed to solve the twisting problem. Thus, Bonsignore clearly teaches away from the teachings of Shanley suggested by the examiner.

Third, the combination of Bonsignore and Shanley is improper because the proposed modification would change the principle of operation of Bonsignore, which is prohibited by MPEP 2143.01 (set forth in more detail in the previous Amendment). Particularly, modifying Bonsignore with the alleged teaching of notches for bending, as suggested by the examiner, would change the principle of operation of Bonsignore.

That is, the widths of the struts, hoops and bridges would no longer be less than or equal to the wall thickness of the tube, and the modified Bonsignore stents would not operate to prevent twisting of struts because the preferred stress distributions would not be attained, as intended.

In view of the foregoing, neither Bonsignore nor Shanley discloses notches for facilitating flaring of the end struts. Moreover, based on Bonsignore's disclosure of maintaining a wall thickness equal to or greater than the widths of the struts, hoop, and bridges of the stent, there not only would be no need or motivation to notch a stent wall, but there would be a definite teaching away of such notching by Bonsignore itself. Additionally, if the stents of Bonsignore were notched, the operation of the wall thickness being equal to or greater than the widths of the struts, hoop, and bridges of the stent to maintain desired stresses distributions and prevent strut twisting would be defeated, and thus the principle of operation of the Bonsignore stents would be improperly changed.

Therefore, applicants submit that Bonsignore and Shanley, both independently and in combination, fail to disclose or suggest the features of independent claim 18. Further, claims 19-22 and 27, which depend from claim 18, are allowable for at least the same reasons that claim 18 is allowable as well as for their own unique features. Accordingly, applicants request that the § 103 rejection of claims 18-22 and 27 be withdrawn.

In view of the foregoing amendments and remarks, applicants respectfully request prompt examination of this application and timely allowance of the pending claims.

The Office Action contains characterizations of the claims and the related art with which applicants do not necessarily agree. Unless expressly noted otherwise, applicants decline to subscribe to any statement or characterization in the Office Action.

If the Examiner believes a telephone conversation might advance prosecution, the Examiner is invited to call applicants' undersigned attorney at 617-933-4444.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 02-3038.

Respectfully submitted,

/jay a. stelacone/

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Jay A. Stelacone, Reg. No. 42,168  
Rissman Jobse Hendricks & Oliverio, LLP  
Customer Number 21127  
Tel: (617) 367-4600  
Fax: (617) 367-4656